K 040849

510(k) Summary

Applicant	Cole & Associates 633 Skokie Blvd. Suite 280 Northbrook, IL 60062
Manufacturer	pIfR Privat-Institut für Reha-Anwendungen GmbH & Co. Medizintechnik KG Frau Klaus Leinorstr. 2 85757 Karlsfeld
Device Name	Mentamove®
Common Name	Powered Muscle Stimulator, Biofeedback Device (per 21 CFR 890.5850 and 21 CFR 882.5050)
Summary of Substantial Equivalence	Mentamove® is substantially equivalent in respect to the intended use, design and method of operation of the Neuromove NM900 manufactured by Dan Med, Inc. (K012885).
Device Description	Mentamove is a microprocessor controlled medicotechnical instrument that provides electromyography (EMG)-triggered neuromuscular electrical stimulation ("EMS").
Intended Use and Indications	Mentamove is indicated for use in the rehabilitation of victims of stroke. It utilizes stroke victims' electromyographic signals to guide the application of electrical muscle stimulation. This stimulation helps stroke victims to relearn voluntary motor functions of the extremities.
Technological Characteristics	Mentamove is user-friendly with self-explanatory instructions for use via display and therefore simple for the patient to do exercises at home, including automatic adjustment of all practice parameters and simple electrode placement. Optical signal transmission also facilitates the exercise of the patient. Mentamove automatically gauges therapeutic advances of the patient. Mentamove works with amplitude modulated electrical current of middle frequency convenient for the patient ("soft" electrical current, physiologically adjusted).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 - 2004

Cole & Associates
C/O Richard O. Wood
Bell, Boyd & Lloyd, LLP
70 W. Madison St.
Suite 3300
Chicago, Illinois 60602

Re: K040849
Trade/Device Name: Mentamove®
Regulation Number: 21 CFR 890.5850 and 21 CFR 882.5050
Regulation Name: Powered Muscle Stimulator and Biofeedback
Regulatory Class: Class II
Product Code: IPF and HCC
Dated: September 21, 2004
Received: September 22, 2004

Dear Mr. Wood:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number K040849

Device Name: Mentamove®

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

for

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040849